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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER	
MARTINELL, J	
ART UNIT	PAPER NUMBER
174	5

DATE MAILED: 06/06/83

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 3/21/83 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-25 are pending in the application.
   Of the above, claims 1-19 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 20-25 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Applicant's election with traverse of Group II, Claims 20-25 in Paper No. 4 is acknowledged. Applicant's argument is not deemed persuasive because applicants agree that the compositions of Group II are not defined by the methods of Group I.

The requirement is still deemed to be proper and is therefore made FINAL.

Claims 1-19 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 4.

The disclosure is objected to because of the following informalities: "PNAS" should be changed to --Proc. Natl. Acad. Sci. USA-- wherever it occurs (e.g., page 24, line 31). Appropriate correction is required.

Claims 20-25 are rejected under 35 U.S.C. 101 because the invention as disclosed is inoperative and therefore lacks utility. There is no showing that cloned genes coding for immunoglobulin chains can be transcribed and translated in any bacterial host nor that the polypeptides (i.e., if such polypeptides were to be synthesized) would be "assembled" post-translationally into a functioning antibody (i.e., retain the binding specificity of the original cloned

gene product) nor that such properly assembled antibody is recoverable in active form.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claim 22 is vague and indefinite in the recitation of "domain" (line 4). Claim 23 contains an obvious typographical error as it makes no sense.

Claims 20-25 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the disclosure at pages 1-43 of the specification. See MPEP 706.03(n) and 706.03(z). The claims are broader than the enabling disclosure because applicants assert that the mammalian immunological system is unique (page 1, first paragraph of the instant application), yet the claims are not limited to mammalian immunoglobulins.

Claims 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The claims are vague and indefinite and inaccurate in the recitation of "free of the constant region" (claim 20, line 7) and "translation of a DNA

sequence" (Claim 20, line 6). Applicants do not define what they mean by "free of..."; this phrase may be interpreted to mean "non-contiguous with" and thus render the structure readable on naturally occuring immunoglobulin genes (see Leder, cited here as of interest). The phrase "translation of a DNA sequence" is inaccurate because DNA is normally transcribed in vivo, not translated and because the synthesis of polypeptides by translation in vivo requires an mRNA intermediate.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in

> public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by any one of Sharon et al, Rosemblatt et al or Pawlowski et al. The broad language f the claims describes no more than any

antibody; hence the compositions of any of the references read on the claims.

Claims 20-25 are rejected under 35 U.S.C. 103 as being unpatentable over any one of Zakut et al, Seidman et al, or Early et al (Cell) in view of Amster et al. Each of the primary references teaches the molecular cloning of immunoglobulin genes. Applicants acknowledge that the sequences disclosed in the instant application are derived from Seidman et al and Early et al (see pages 28 and 29 of the instant application). Amster et al suggests the productionof specific antibody molecules in bacteria by recombinant DNA cloning and expression methods. Amster et al further teach the synthesis of a portion of the variable region of an IgG as acknowledged by applicants (page 2, lines 24-29). It would be obvious for the ordinary skilled artisan to express the genes any of the primary references as taught by Amster et al to arrive at the claimed compositions.

Claims 20-25 are rejected under 35 U.S.C. 103 as being unpatentable over any one of Zakut et al, Seidman et al, or Early et al (Cell) in view of Amster et al as applied to claims 20-25 above, and further in view of either one of applicants' admitted state of the prior art (see page 40, first full paragraph) or

Ptashne et al. Applicants admit the expression vector that may be used to be old. Ptashne et al teach the expression of foreign genes in bacteria. It would be obvious for the ordinary skilled artisan to express cloned immunoglobulin genes in either the manner admitted by applicants to be old, or by the method of Ptashne.

JM
J. MARTINELL/mjg
(703) 557-3615
May 18, 1983

THOMAS G. WISEMAN
EXAMINER
GROUP ART UNIT 172